No. 11-725

IN THE

Supreme Court of the United States

THE ASSOCIATION FOR MOLECULAR PATHOLOGY, ET. AL.,

Petitioners,

v.

MYRIAD GENETICS, INC., ET. AL.,

Respondents,

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* KNOWLEDGE ECOLOGY INTERNATIONAL IN SUPPORT OF PETITIONERS

Krista L. Cox
Counsel of record
Knowledge Ecology International
1621 Connecticut Ave. NW, Suite 500
Washington, DC 20009
(202) 332-2670
krista.cox@kieonline.org

Counsel for Amicus Curiae

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INTEREST OF AMICUS CURIAE[1]

Knowledge Ecology International ("KEI") is an international nonprofit, nongovernmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. In particular, KEI is focused on the management of these resources in the context of social justice. KEI is drawn to areas where current business models and practices by businesses, governments or other actors fail to adequately address social needs or where there are opportunities for substantial improvements. Among other areas, KEI has expertise in access to medicines and medical technologies.

KEI is concerned about the implications of the Federal Circuit decision in the present case because it will have far-reaching consequences for the future of patent law and public health. As an advocate of new incentive and financing models for biomedical innovation and the proponent of several mechanisms for stimulating investments and promoting innovation outside of the patent regime, KEI has concerns that the Federal Circuit decision in the present case ignores these

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[1] The parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the amicus curiae's intention to file this brief. No counsel representing any party to the case authored this brief in whole or in part and no counsel or party made any monetary contribution to the preparation or submission of the brief.

alternatives and focuses exclusively on patent rewards. If the Federal Circuit decision is allowed to stand, that decision could stifle innovation and negatively impact patients as well as future innovation.

SUMMARY

The present case presents a question that is of fundamental importance for the future of the future of patent law and will have impacts on public health. Little guidance as to whether human genes are patentable exists as the lower court decision resulted in a fractured, splintered opinion and the Executive Branch is also divided in this area.

The goal of the patent system is to encourage the progress of science. However, if the Federal Circuit decision is allowed to stand, this goal will be contravened and the progress of science will be hindered. Furthermore, the lower court decision ignores the numerous non-patent mechanisms that can provide a more appropriate reward for the isolation of human genes.

REASONS FOR GRANTING THE PETITION

I. THE QUESTION OF WHETHER HUMAN GENES ARE PATENTABLE RAISES FUNDAMENTALLY IMPORTANT CONSEQUENCES FOR THE FUTURE OF PATENT LAW.

A. The Legal Community Needs Guidance With Regard to the Applicability of Section 101 to DNA

No clear reasoning exists with regard to the applicability of Section 101 to DNA because the four federal judges that have previously considered this case have each had different opinions in reliance on different reasoning. The Federal Circuit in *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (2011) resulted in a three-way split in reasoning and no true majority reasoning emerged. Although two of the three of the judges hearing the case agreed that isolated DNA fragments are patentable, they arrived at their conclusion using drastically different reasoning. Significantly, all three Federal Circuit judges hearing the case relied upon this Court's decision in *Diamond v. Chakrabarty* in coming to its conclusion. 447 U.S. 303 (1980). Thus, all three judges reached different conclusions and provided for different

interpretations of *Chakrabarty*, giving the legal community little guidance in this area.

Without a true majority opinion, it is immensely difficult for the legal community to grasp the holding of this case or apply it to future cases. This Court has in fact opined that when no single rationale explaining the decision is agreed upon by the majority of judges, the holding of the court should be viewed as the position taken by the concurring judgments on the narrowest ground. *Marks v. United States*, 430 U.S. 188, 193 (1977). However, the poorly defined "narrowest ground" doctrine is often impossible to apply. *See Nichols v. United States*, 511 U.S. 738 (1944); *Seminole Tribe v. Florida*, 517 U.S. 44 (1996). The confusion created from interpreting splintered and fractured decisions is in "itself a reason to reexamine that decision." *Nichols* at 745-46.

This case represents a novel question for this Court because although it has heard several patent cases regarding method patents, it has not addressed the patentability of human DNA. Furthermore, not since its ruling in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) has it addressed compositions of matter under 35 U.S.C. Section 101. It is critical for this Court to clarify not only the bounds of Section 101, but also the application of *Chakrabarty* to products such as

human genes and isolated DNA. Given the advances of technology and science over the past thirty years and continuing growth of biotechnology and other sectors, this case is ripe for this Court's consideration.

B. Even the Executive Branch is Fragmented and Divided With Regard to Patentablity of Genes

In addition to the highly fractured and divided opinions of the four lower court judges who have decided the present case, the Executive branch is also fragmented with regard to the patentability of genes and isolated DNA. Although the USPTO granted the patents-at-issue and authorized the patenting of isolated DNA, when the present case reached the Federal Circuit, USPTO did not sign the brief submitted on behalf of the United States. Br. for the United States as Amicus Curiae in Supp. Of Neither Party, *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office,* 653 F.3d 1329 (F3d. Cir. 2011) (No. 2010-1406). The brief submitted by the United States as *amicus curiae* took the position that isolated DNA and human genes could not receive patent protection, though cDNA remained patent eligible. *Id.* at 1. The Solicitor General argued this position on behalf of the United States during oral arguments before the Federal Circuit.

As noted by Judge Bryson's dissenting opinion, the USPTO's position was "substantially undermined by the position the government has

taken in this case" when the Department of Justice advocated for the exclusion of isolated DNA from patentability. While both the USPTO and Department of Justice are part of the Executive Branch, the decision to intervene in the case at the appellate level suggests a change in position from the time USPTO granted of the patents-at-issue to the present.

With the Executive Branch providing conflicting views on whether the claims-at-issue should receive patent protection, coupled with the highly fragmented three-way split in reasoning by the Federal Circuit, no clear guidance exists with regard to the patentability of human genes and isolated DNA. It is therefore necessary for this Court to provide guidance in this area as to the patent eligibility of the claims-at-issue and the scope of Section 101.

C. The question as to whether human genes or isolated DNA is patent eligible will have far-reaching effects on genetic research, medical innovations, the future of patent law and public health.

As noted above, uncertainty exists as to the bounds of Section 101 and the applicability of the reasoning under *Chakrabarty*. While all three Federal Circuit judges relied upon *Chakrabarty* in

reaching his or her decision, each interpreted this case differently which resulted in a three-way split in reasoning. The ambiguity of this holding creates uncertainty not only for the specific claims-at-issue, but also for the future of genetic research.

The impact of the Federal Circuit decision not only implicates alternative testing for the BRCA1 and BRCA2 genes, but also for future research and development with respect to these and other patented genes. Scientists and researchers have expressed reluctance to conduct research and development where patents on genes exist because of fear of possible litigation.

Patients will, predictably, face harm as a result of the Federal Circuit ruling. Specifically, patients wishing to undergo diagnostic testing for the BRCA1 and BRCA2 gene whose insurance does not cover the test must make a choice to pay Myriad's monopoly price of more than $3,000 or forego the diagnostic. Myriad, because it owns an exclusive monopoly over the genes, can prevent all research on the BRCA 1 and BRCA2 genes. This monopoly operates to the detriment of the public who cannot obtain a second opinion even where, for example, Myriad's test had a twelve-percent error rate or failed to identify all known mutations of the gene. *See* Tom Walsh, et. al., *Spectrum of Mutations in BRCA1, BRCA2, CHECK2, and TP53 in Families at High Risk of Breast Cancer*, 295 JAMA 1369, 1386 (2006).

The impact of this case extends beyond the BRCA1 and BRCA2 genes, even when narrowly evaluated in the context of Myriad's claims-at-issue. A study performed by Duke University's Department of Biostatistics and Bioinformatics found that the patents-at-issue would preempt a broad range of genetic tests, extending beyond those directly linked to BRCA1 and BRCA 2 research. Thomas B. Kepler, et. al., *Metastatasizing patent claims on BRCA1,* Genomics (May 2010), *available at* http://www.elsevier.com/framework_products/promis_misc/kepler_crossman_cook_deegan.pdf. One of the claims upheld by the Federal Circuit broadly covers fifteen nucleotides that occur on the BRCA1 and BRCA2 genes, but which also occur elsewhere in the genome. *Id.* at 2-3. Therefore, the impacts even in the narrower context of the patents claimed in the present case will affect diagnostic testing beyond the BRCA1 and BRCA2 genes.

II. THE GOAL OF THE PATENT SYSTEM IS TO ENCOURAGE PROGRESS AND THE IMPACT OF THE PATENT ELIGIBILITY OF HUMAN GENES IS CRITICAL TO THE PROGRESS OF SCIENCE AND USEFUL ARTS AND TO THE PUBLIC HEALTH.

A. Where Patent Protection Improperly Preempts All Other Uses, Progress of Science Is Hindered

The Constitutional rationale for allowing Congress to create laws permitting inventors to have a limited monopoly over their inventions is to "promote the Progress of Science and useful Arts." U.S. Const. art. 1, §8, cl. 8. The Constitution thus sets forth the goal of advancing scientific progress and the "embarrassment of an exclusive patent" is justified only because these monopolies serve the "benefit of society." *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (1966) (*quoting* Thomas Jefferson (internal citation omitted)).

It is well settled that, although Congress has wide latitude in creating patent laws, it "may not overreach the restraints imposed by the stated constitutional purposes." *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966). Indeed, although the Constitution grants Congress the power to make patent laws, the clause "is both a grant of power *and a limitation*. This qualified authority . . . is limited to the promotion of advances in the useful arts." *Id.* at 5 (emphasis added). The Constitutional standard for patent law, that is to promote progress, "may not be ignored." *Id.* At 6.

As a result of this limitation, this Court has found that patents may not be granted where the effect would be "to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Id.* This Court

has repeatedly recognized the limits of patentability and "the laws of nature, physical phenomena, and abstract ideas have been held not patentable." *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (*citing Parker v. Flook*, 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O'Reilly v. Morse*, 56 U.S. 112, 121 (1854); *Le Roy v. Tatham*, 55 U.S. 175 (1853)). Mere discoveries of naturally occurring objects may not receive patent protection. *Id.* at 312-313 (Objects found in nature and unaided by the hand of man "must be free to all mankind" and a "new mineral or plant discovered in the wild would not be patent eligible."). Thus, a newly discovered mineral or Newton's law of gravity are "manifestations of . . . nature, free to all men and reserved exclusively to none." *Chakrabarty* at 309 (*citing Funk Brothers*, 333 U.S. 130 (internal quotations omitted).

Furthermore, monopolies that prohibit all others from creating the same effect or process by any other means effectively discourages scientific progress and contravenes the policy of the Patent Act. *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853). More recently, in the case, *Bilski v. Kappos*, this Court noted that preemption remains an important factor in determining the scope of patentability under Section 101 of the Patent Act. 130 S.Ct. 3218 (2010). Here, patent protection on

the BRCA1 and BRCA2 genes completely forecloses and preempts all other uses of the product, thereby contravening the purpose of the patent system.

B. Products of Nature, Laws of Nature and Natural Phenomena, Such as the Claims-At-Issue Are Not Patent-Eligible

This Court, in applying Section 101 of the Patent Act to compositions of matter, determined that three specific types of claims have been categorically removed from patent eligibility. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). These claims include "the laws of nature, physical phenomena, and abstract ideas." *Id.* *See also Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

In his opinion, Judge Lourie incorrectly suggested that a categorical rule excluding isolated genes from patent eligibility could not be supported by this Court's jurisprudence which "repeatedly rejected new categorical exclusions from §101's scope." *Ass'n Molecular Pathology* at 1353. However, this Court has in fact excluded entire categories of subject matters from patent eligibility in its previous jurisprudence interpreting the bounds of Section 101 and the Federal Circuit decision ignores such precedent.

Of particular applicability to the present case, and as noted above, this Court has held all natural phenomena, laws of nature and abstract

ideas ineligible for patent protection. Chakrabarty at 309; *Dieher* at 185; *Funk Bros. Seeds Co. v. Kalo Co.*, 333 U.S. 127 (1948). In addition to excluding this wide category of objects from patentability, this Court has also made specific exclusions. For example, wood pulp and paper pulp were denied patentability as objects known to be in existence prior to the patent claims. *American Wood Paper Co. v. Fiber Disintegrating Co.*, 90 U.S. 566 (1874).

Under such jurisprudence, lower federal courts have similarly made exclusions from patentability, particularly for purified materials or objects obtained through extraction without further human processing. Such exclusions include purified uranium, *In re Marden*, 47 F.2d 957 (C.C.P.A. 1931), purified vanadium, *In re Marden*, 47 F.2d 958 (1931), purified tungsten, *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928), and vitamin C that was purified from lemon juice, *In re King*, 107 F.2d 618 (C.C.P.A. 1939), among others. Thus, while these lower courts did not specifically invalidate wholesale categories of subject matter from patent eligibility, these cases, in the aggregate, illustrate an exclusion of naturally occurring substances from patentability.

The present case, involving purified or isolated DNA, represents products that are merely

naturally occurring phenomena. They have been obtained through extraction and, while involving human effort to isolate the DNA, the claims represent no more than products of nature. The isolated BRCA1 and BRCA2 genes are not markedly different from those found in nature and, as a result, should not receive patent protection. The limitation of our patent system excluding products of nature is necessary to ensure that the purpose of the patent regime—to promote the progress of science—is fulfilled and that unnecessary roadblocks to future research and development are not erected.

III. NON-PATENT MECHANISMS CAN AND SHOULD ENCOURAGE PROGRESS WHERE PATENTS ARE AN INAPPROPRIATE, UNNECESSARY, INSUFFICIENT, OR BURDENSOME REWARD

The most common and superficially appealing justifications for liberal standards to patentable subject matter are those that assert, without evidence, that the necessity of patents is to protect and reward investments in the development of new products.

The false argument that patents are necessary to protect investments is belied both by the known shortcomings of patents as an incentive mechanism, and the growing proliferation of non-patents mechanisms to stimulate R&D.

In certain areas of innovation, patents do not provide adequate incentives for research and development and other mechanisms to reward innovation are needed. Also, with respect to the claims-at-issue, patent protection can effectively blocks further research and development, and discourage investments.

A report by the Department of Health and Human Services Advisory Committee on Genetics, Health, and Society concluded that gene patents were not necessary to provide incentives for research or development of clinical testing. Dep't of Health & Human Serv., Sec'y's Advisory Comm. On Genetics, Health, and Soc'y, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (Apr. 2010), *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf. This report also noted that gene patents harmed patient access to genetic testing and denied quality assurance of such tests. *Id.* Because patents provide an inappropriate and burdensome incentive in the case of isolated-DNA or human genes, other mechanisms should be explored.

A wide range of non-patent incentives exist to encourage research and discovery. Mechanisms to protect, reward and induce investment into innovation across broad sectors, such as trade secret protection, often take the

place of patent incentives. Trade secrets, while having their own shortcomings in terms of limiting access to knowledge, are used to promote investments in new medical products, including in particular, for medical diagnostic technologies and biotechnology drugs. Iraj Daizadeh, et. al., *A general approach for determining when to patent, publish, or protect information as a trade secret*, 20 Nat. Biotech1053-1054 (2002).

Beyond trade secret protections are a wide range of new *sui generis* forms of intellectual property that are used in parallel to the patent system, and often when patent protection is not available. One type of *sui generis* protection that has become quite common is the application of time limited exclusive rights to rely upon test data used to register new drugs or vaccines. Food, Drug and Cosmetics Act, New Drugs, 21 U.S.C. §355. These rights include 5 years of test data protection for new chemical entity pharmaceutical products, and 12 years of test data protection for new biologic drugs. *Id.* Another type of non-patent right is the marketing exclusivity granted for the development of new "orphan" drug indications, or to reward investments in clinical trials for pediatric patents. Internal Revenue Code, Clinical testing expenses for certain drugs for rare diseases or conditions, 26 U.S.C. §45C. The U.S. Government gives a 50 percent tax credit for investments in clinical trials for orphan drugs, and the U.S. Congress is considering legislation to grant 5 years of market exclusivity for new antibiotic drugs, that would work as either as a supplement to or independent

of patent protection. *Id.* To simulate R&D in treatments for rare tropical diseases, the U.S. Congress has created a new "Priority Review Voucher," that provides for a transferable right to an accelerated consideration of new drug approvals as a reward for registration drugs for treatments like cholera or leprosy. Food, Drug and Cosmetic Act, Priority Review to Encourage Treatments for Tropical Diseases, 21 U.S.C. §360n.

In addition to these existing and expanding mechanisms, a new class of reward investment in medical research and development are under consideration, both internationally and domestically, that involve cash innovation inducement prizes, to stimulate investments in public health, and other areas of public and private interest.[2]

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[2] *See, e.g.*, James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 Chi.-Kent L. Rev. 1521-24 (2007); James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 Annals Health L. 155-186 (2009); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes and Research Contracts,* 73 American Economic Review 691-707(1983); Burton Weisbrod, *Solving the Drug Dilemma,* Wash. Post (Aug. 22, 2003) at A21; T. Kalil, *Hamilton Project and Brookings Institution, Prizes for Technological Innovation* (2006); Bruce G. Charlton, *Mega-Prizes in Medicine: Big Cash Awards May Stimulate Useful and Rapid Therapuetic Innovation*, 68 Medical Hypotheses 1-3 (2007); L. Brunt, J. Lerner & T. Nicholas, Inducement Prizes and Innovation (2008); *Selected Innovation and Reward Programs*, KEI Research Note 2008:1; K. Davidian, Prizes, Prize Culture and NASA's Centennial Challenges (2004); Julien Penin, *Patents versus ex post rewards: A new look*, 34 Research Pol'y 641 (2005);

The World Health Organization has called for new proposals to incentivize research and development "addressing the de-linkage of the costs of research and developments and the price of health products and methods for tailoring the optimal mix of incentives to a particular condition or product with the objective of addressing diseases that disproportionate affect developing countries." Global strategy and plan of action on public health, innovation and intellectual property, World Health Assembly 61.21 (2008). Such de-linkage includes the awards of prizes. *Id.* at Annex, element 5.3(a).

In the 112th Congress, two bills were introduced in the Senate that proposed large cash prizes as an alternative to an exclusive patent monopoly, including S. 1137 and S. 1138. Medical Innovation Prize Fund Act, S.1137, 112th

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J.G. Morgan, *Inducing Innovation Through Prizes*, 3 Innovations: Technology, Governance, Globalization 105 (2008); W.A. Masters, *Prizes for innovation in African agriculture: a framework document* (2004), available at http://ww.eart.columbia.edu/cgsd/prizes; Joseph E. Stiglitz, *Scrooge and Intellectual Property Rights: A Medical Prize Fund Could Improve the Financing of Drug Innovations*, 333 British Medical Journal, 129 (2006); Ron Marchant, *Managing Prize Systems: Some Thoughts on the Options*, 2 Knowledge Ecology Studies (2008); James Love, *The Role of Prizes in Developing Low-Cost, Point-of-Care Rapid Diagnostic Tests and Better Drugs for Tuberculosis* (2008), http://www.keionline.org/misc-docs/Prizes/prize_tb_msf_expert_meeting.pdf.

Cong. (2011); Prize Fund for HIV/AIDS Act, S.1138, 112th Cong. (2011). One of these bills would apply to all prescription drugs, while the other would limit its application to HIV/AIDS drugs.

Prizes may be particularly relevant in areas where products are not eligible for patents or where it would be inefficient or harmful to permit exclusive monopoly rights to be enforced. Areas where unrestricted access to basic information or discoveries is critical to the progress of science, patents act as a barrier to further innovation and do more harm than good. *See* John Sulston & Georgina Ferry, The Common Thread (2003); Aaron S. Kesselhein & Jerry Avorn, *University Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850-54 (2005).

In the present case, patents are not an appropriate mechanism for rewarding investments in the isolation of DNA or the identification of genes. Patents in the area of human genes are burdensome, foreclosing future research and development and preempting all other uses of the gene in direct contradiction to the purposes of the patent system. Thus, other, more viable forms of incentives exist and should be used to reward research and development in this area and stimulate innovation.

CONCLUSION

The U.S. patent system operates to provide incentives for research and development, but is not without its limits. This case presents questions that are fundamentally important to the patent system, the future of research and development and public health. No clear guidance has emerged from the lower court decisions in the case and, essentially, a four-way split in reasoning exists with regard to the application of this Court's precedent and the language of Section 101. Moreover, the lower court decision ignores the fact that alternative incentive mechanisms exist to incentivize research and development in areas where a patent monopoly does not provide an appropriate reward.

For the reasons stated above, this Court should grant the petition for certiorari.

Respectfully submitted,

Krista L. Cox
Counsel of record
Knowledge Ecology International
1621 Connecticut Ave. NW
Suite 500
Washington, DC 20009
(202) 332-2670
krista.cox@kieonline.org

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